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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,938	08/21/2001	Pathiraja A. Gunatillake	1207.008US1	7489

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EXAMINER	
SERGENT, RABON A	
ART UNIT	**PAPER NUMBER**
1711	4

DATE MAILED: 11/29/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

T.D-4

Office Action Summary

Application No.	Applicant(s)
09/933,938	Gunatillake et al.
Examiner	**Art Unit**
Rabon Sergent	1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *63-121* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *63-121* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Claims 63-121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Within claim 63, it is unclear if the soft segment must be formed from a macrodiol, a macrodiamine, and a compound of formula (I). It is unclear how to interpret "at least one of"; the language can be interpreted to mean that only one of the aforementioned compounds must be used. Furthermore, the second chain extender is not mutually exclusive from the formula (I) chain extender, and the macrodiamine is not mutually exclusive from the compound of formula (I). Additionally, the last three lines of claim 63 are confusing; it is unclear how the same compound can perform the different functions specified within the claim. There is no language which governs how the formula (I) compound is altered to meet the different utilities or applications. The compound of formula (I) is not mutually exclusive from the formula (I) chain extender.

Within claims 63, 104, 111, and 112, the formula (I) structure is confusing, because the R group appears to be attached to R_5. The nitrogen should be attached to R_5. Also, within claim 111, the structure has not been identified as formula (I).

Within claim 72, 1,3-diaminocyclohexane has been spelled incorrectly.

Within claims 73 and 74, the type (i.e.; weight) of percent has not been specified.

Within claim 76, it is unclear with respect to which isomers of the compounds are being referred to.

Within claims 82, 83, 87, and 91 it is unclear what is meant by PDMS; this is not a well-known abbreviation.

Within claim 102, it is improper to refer to the trade name, since the composition denoted by the trade name is not fixed with respect to the components of the composition.

Within claims 86, 93, 100, 104, 111, and 112, it is improper to define the variables n, p, and q using "about", because it cannot be determined exactly which compounds are defined or encompassed by the structure, due to the variation or uncertainty that "about" introduces into the structure. For example, it cannot be clearly determined what value is denoted by "about 20".

It appears that the dependencies of claims 96 and 107 are incorrect.

Within claim 98, the use of "based" renders the claim indefinite, because it is unclear to what extent the polycarbonate is "based" on or derived from silicon.

Within claims 104, 109, and 112, it is unclear how to interpret the last part of the claim which lists diamine chain extenders. Is this language intended to be in the form of a Markush group?

Within claim 111, it is unclear how to interpret part (i) in view of the reference to both macrodiol and macrodiamine and further in view of the use of commas and semi-colons.

Within claim 121, the significance of the use of commas and semi-colons is unclear.

Within claims 113-117, it is not clear that the relative terms, "resistant" and "improved", and the "useful as" language further patentably limit or distinguish the claims. It is not clear that the language constitutes definitive limitations.

2. Claims 81-103 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Within claims 81, 89, 90, 96, and 97, applicants have failed to specify the type of molecular weight (i.e.; number average or weight average) or how it has been determined. This information is necessary to adequately identify the components.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 63-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szycher et al. ('627) or WO 98/13405 or JP 4-248826, each in view of Li et al. ('724) and Ohtaki et al. ('085).

The primary references disclose the production of polysiloxane-polyurethane (urea) polymers having enhanced biocompatibility wherein active hydrogen group containing polysiloxanes are combined with additional active hydrogen compounds and the resulting mixture is reacted with polyisocyanates to yield polymers having enhanced characteristics.

5. While Szycher et al. and JP 4-248826 disclose that amine functional polysiloxanes may be used, the references further disclose the use hydroxyl functional polysiloxanes. Additionally, none of the primary references disclose the specific use of an amine functional siloxane as a chain extender. However, Li et al. specifically teach the use of amine functional polysiloxane compounds, which overlap applicants' claimed high and low molecular weight compounds, in the production of biocompatible polyureas and polyurethane ureas having improved physical and mechanical properties. Furthermore, Ohtaki et al. disclose the use of amino functional tetraorganodisiloxanes as reactants within polyurethanes.

6. Therefore, since applicants' claimed amine functional polysiloxanes were known reaction constituents for polurethaneureas and since they were known to bestow improved properties, including improved biocompatilibility, to urethanes, it would have been prima facie obvious to utilize them within the compositions of the primary references, so as to arrive at the instant invention.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (703) 308-2982.

RABON SERGENT
PRIMARY EXAMINER

Sergent/af

November 9, 2001